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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Edible Nostoc commune formulations and their use for promoting health					
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ENCLOSED APPLICATION PARTS (check all that apply)					
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Respectfully submitted,

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Date 1-28-04

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REGISTRATION NO. \_\_\_\_\_

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# **Edible *Nostoc commune* formulations and their use for promoting health**

## **Abstract**

The present invention provides novel *Nostoc* formulations comprising *Nostoc commune*, (also known as *Nostoc sphaericum*, or *Nostoc commune* var. *sphaericum*). The present invention relates to *Nostoc* formulations, dietary supplements comprising the *Nostoc* formulations, and food products which include the *Nostoc* formulations and/or the dietary supplements. The present invention also relates to pharmacological compositions comprising the *Nostoc* formulation that may additionally comprise a medicinal composition. The present invention further relates to processes for producing *Nostoc* formulations. In addition, the present invention relates to methods for promoting the health of an individual utilizing the *Nostoc* formulations, dietary supplements, food products and/or pharmacological compositions of the present invention.

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## Description

### BACKGROUND OF THE INVENTION

The cyanobacterium *Nostoc commune*, also known as *Nostoc sphaericum*, or *Nostoc commune* var. *sphaericum*, appears as spherical macroscopic colonies (“pearls”) in natural habitats. *Nostoc commune* is a filamentous, nitrogen-fixing cyanobacterium belonging to the family of *Nostocaceae* in the order of *Nostocales* (Komarek and Anagnostidis, 1989). In natural habitats, such as rice paddies, shallow streams, water pounds, and large open fields, *N. commune* can form spherical macroscopic colonies consisting of filaments embedded in a gelatinous matrix. The size of colonies ranges from tens of mm to tens of cm in diameter with the largest described being 2.6 kg wet weight (Dodds et al. 1995). The colonies range in colors from yellow-green to red-brown, and dark green to black (Potts, 2000). The filaments are unbranched and largely twisted, and consist of mostly vegetative cells with a few heterocysts occurring in the middle of a filament. Reproduction of *N. commune* takes place in four different ways, depending on environmental conditions: 1) single cells of *N. commune* fragmented from filaments can form new colonies; 2) akinete formation and germination; 3) hormogonia disperse and form new colonies; 4) large colonies can bud off to form separate colonies (Dodds, et al., 1995).

### SUMMARY OF THE INVENTION

The present invention provides edible *Nostoc commune* formulations, dietary supplements, and food products (including medical foods) comprising the *Nostoc commune* formulations and/or dietary supplements. The present invention also provides pharmaceutical compositions.

An edible *Nostoc commune* formulation of the present invention includes fresh biomass or dried powder of *Nostoc commune*. The *Nostoc commune* formulation may further include proteins, fatty acids, amino acids, polysaccharides, vitamins, natural pigments, minerals.

A dietary supplement of the present invention comprises a *Nostoc commune* formulation of the present invention. The dietary supplement may further comprise ingredients such as herbals or herbal extracts, algal biomass or their extracts, fungi extracts, enzymes, a fiber source, minerals, vitamins and the like.

A food product of the present invention comprises a *Nostoc commune* formulation of the present invention and/or a dietary supplement of the present invention. The food product may further comprise additional ingredients, such as herbals or herbal extracts, algal biomass and their extracts, and fungi extracts, enzymes, a fiber source, minerals, vitamins and the like.

A pharmaceutical composition of the present invention comprises a *Nostoc commune* formulation of the present invention in a pharmacologically effective amount. The compositions may additionally comprise prescription medicines or non-prescription medicines. The combinations may advantageously produce one or more of the following effects:

- 1) additive and/or synergistic benefits;
- 2) reduction of the side effects and/or adverse effects associated with use of the prescription medicine in the absence of the *Nostoc commune* formulation; and/or

3) the ability to lower the dosage of the prescription medicine in comparison to the amount of prescription medicine needed in the absence of the soy formulation.

The *Nostoc commune* formulations, dietary supplements, food products and/or pharmaceutical compositions of the present invention may advantageously be utilized in methods for promoting the health of an individual.

The *Nostoc commune* formulations, dietary supplements, food products and pharmaceutical compositions of the present invention may also provide proteins, fatty acids, amino acids, polysaccharides, vitamins, natural pigments, minerals. The proteins, fatty acids, amino acids, polysaccharides, vitamins, natural pigments, minerals provided by the *Nostoc commune* formulations, dietary supplements, food products and pharmaceutical compositions of the present invention may provide numerous health benefits to an individual.

Further details and advantages of the present invention are provided in the following more detailed description.

## **DETAILED DESCRIPTION OF THE INVENTION**

(1). The present invention provides an edible *Nostoc commune* formulation, which includes fresh biomass or dried powder of *Nostoc commune*. In another aspect, the present invention provides a *Nostoc commune* formulation comprising protein, fatty acids, polysaccharides and pigments.

The *Nostoc commune* formulation of the present invention may take many forms. For example, the *Nostoc commune* formulations of the present invention may be in powder form. Alternatively, the *Nostoc commune* formulations may be in tablet, capsule, or liquid form. In addition, the *Nostoc commune* formulations of the present invention may be included within a dietary supplement, or within food items, such as nutrition bars, liquid drinks, cereals, dairy products, etc. and in a food product of the present invention.

(2). The *Nostoc commune* formulation of the present invention may be utilized in dietary supplements. In one aspect, a dietary supplement of the present invention comprises the *Nostoc commune* formulation of the present invention. A serving of a dietary supplement of the present invention could comprise 1 to 10 gram of a *Nostoc commune* formulation of the present invention.

A dietary supplement of the present invention may be in any digestible form, including a powder, a tablet, a capsule or in liquid form. A dietary supplement of the present invention may also be agglomerated and/or otherwise treated to improve solubility, digestibility or other aspects of the dietary supplement.

As will be understood by those of ordinary skill in the art, a dietary supplement of the present invention may also include ingredients such as herbals or herbal extracts, algal biomass or their extracts, fungi extracts, enzymes, a fiber source, minerals, vitamins and the like.

(3). The present invention provides a digestible food product, which includes fresh or dried biomass of *Nostoc commune*. The food product of the present invention comprises a *Nostoc commune* formulation containing protein, fatty acids, polysaccharides and pigments.

The food product may further comprise additional components including preservatives, flavorings, vitamins, minerals and the like, including but not limited to calcium phosphate, soy lecithin, salt, potassium, chloride, artificial and natural flavors, carragenenan, carboxymethylcellulose, xanthan gum, water or milk. Among the carbohydrates suitable for use in the present invention are included fructose, glucose, dextrose, maltodextrin and corn syrup solids.

A food product of the present invention may also be produced in a lower calorie form by substituting an artificial sweetener for all or a portion of the sugars. Suitable artificial sweeteners include sucralose (Splenda.TM.), aspartame, saccharin and SinetK.TM. (acesulfurame K). Plant derived sweeteners such as stevia are also suitable.

A food product of the present invention may take many forms, including a powder for dispersing in a liquid, a tablet, a bar, liquid drinks, a cereal, a dairy product, etc. A food product of the present invention may further include herbals or herbal extracts, algal biomass or their extracts, fungi extracts, enzymes, a fiber source, minerals, vitamins and the like.

(4). The present invention provides a pharmacological composition comprising a *Nostoc commune* formulation of the present invention. The present invention provides a pharmacological composition comprising a *Nostoc commune* formulation of the present invention and further comprising a medicinal composition. Suitable medicinal compositions include, but are not limited to the medicinal compositions, drugs and/or prescription drugs utilized in cholesterol lowering therapy; bone strengthening therapy; endometrial therapy; cancer therapy, including chemotherapy; Alzheimer's therapy; ulcer therapy; prostate therapy; skin therapy; renal therapy; blood therapy; lymphatic therapy; lung therapy; nervous system therapy; diabetes therapy; eye therapy and the like. These medicinal compositions include, but are not limited to, Premarin; Fosamax; Raloxifene; Tamoxifen; SERM's (selective estrogen receptor modulators) and other drugs known to those of ordinary skill in the art.

An advantage of a pharmacological composition of the present invention comprising a *Nostoc commune* formulation of the present invention and a medicinal composition is that the combination may have synergistic effects. Therefore it may be possible to use a lesser amount of the medicinal composition in a pharmacological composition of the present invention than the amount traditionally utilized in the absence of a *Nostoc commune* formulation of the present invention, while achieving substantially the same desired therapeutic effects. This feature also may provide an additional advantage of reducing side or adverse effects caused by the medicinal composition due to the lower amount of the medicinal composition utilized.

A method of the present invention for promoting the health of an individual comprises having the individual ingest greater than 50 grams fresh *Nostoc commune* or equivalent dried biomass, preferably greater than 100 grams fresh *Nostoc commune* or equivalent dried biomass, per day.

The present invention also provides methods for promoting and/or enhancing health which include digesting a *Nostoc commune* formulation of the present invention, and/or dietary supplements and/or food items and/or pharmacological compositions which include a *Nostoc commune* formulation of the present invention.